

Appl. No. : 09/447,227
Filed : 11/22/1999

REMARKS

Claims 21, 22, 24, and 28-55 are pending in this application. Claims 21, 28, 30-32, 38 have been amended. New Claims 44-55 have been added. Support for the amendments is found in the specification and claims as filed.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 21-24 have been rejected under 35 U.S.C. §112, first paragraph. Applicants do not agree with the propriety of the rejection, and refer to the data regarding functional devices presented in Figure 7. However, in the interest of progressing the prosecution of the present application, Applicants have amended Claim 21 to recite "a period exceeding 90 days," as previously recited in Claim 23, now cancelled. In view of the foregoing amendments, Applicants respectfully request withdrawal of the rejection.

Claim Rejections - 35 U.S.C. § 102(e)

Claims 21, 28, 32-36, and 38-42 have been rejected under 35 U.S.C. §102(e) as anticipated by Picha (U.S. 5,564,439). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 USPQ2d 1671 (Fed. Cir. 1994). Picha does not disclose every element of Applicants' claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

The pending independent claims recite a method of monitoring glucose levels (Claims 21 and 38) or a method of measuring glucose in a biological fluid (Claims 28-32) that employs a device comprising, *inter alia*, "a sensing membrane proximal to said device, said sensing membrane comprising an enzyme." Picha does not disclose a device incorporating a sensing membrane as recited in the pending claims. Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 21-24, 28, 30, and 32 have been rejected under 35 U.S.C. §103(a) as obvious over Priedel et al. in view of Picha. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally

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available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *See, e.g.*, MPEP § 2142. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Moreover, the totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986). Furthermore, "[k]nown disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness." *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966).

As discussed above in regard to the anticipation rejection, Applicants' pending claims as presently amended recite, *inter alia*, "a sensing membrane proximal to said device, said sensing membrane comprising an enzyme." Priedel et al. discloses electrocatalytic sensors of the catheter type for determining glucose in body fluids. In describing the prior art, Priedel et al. states:

Usually enzyme sensors serve to determine glucose in which glucose oxidase is used and, either the hydrogen peroxide developing upon oxidation or the reduced oxygen content is determined electrochemically. However, because of the use of an enzyme, such sensors do not exhibit the long-term stability required. Namely, the implantation duration of two years called for in medicine cannot be achieved with today's conventional technology.

Priedel et al. at col. 1, lines 13-20. Priedel et al. then describes sensors of a catheter configuration not incorporating an enzyme, the configuration chosen by Priedel et al. for a sensor suitable for long term implantation.

Priedel et al. teaches away from the use of an enzyme in a sensor for long term implantation. Therefore, one skilled in the art, considering the totality of the art, would be discouraged from pursuing a sensor that incorporates an enzyme for long term implantation. Applicants, however, have proceeded contrary to this accepted wisdom and have developed a sensor suitable for long term use that incorporates an enzyme. Accordingly, there is no suggestion or motivation to combine the two references. In fact, Priedel et al. teaches away from such a combination. A *prima facie* case of obviousness therefore cannot be made and Applicants respectfully request that the obviousness rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining

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concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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Dated:

4/14/03

By:



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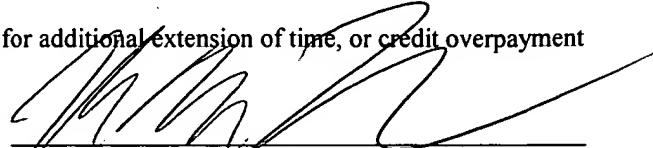
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